HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1171B

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 7 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Seth Mohammed Iqbal
Chairman
G.T. Surgical (PVT) Ltd.
P.O. Box 19, S.I.E.
Sialkot, Pakistan

Dear Mr. Iqbal:

The Food and Drug Administration (FDA) acknowledges receipt of your November 15, 1996, response letter, a copy of which was FAXed to the Office of Compliance on January 26, 1997. The letter was responding to the investigator's observations listed in the form FDA 483, issued at the close of an inspection of your firm located in Sialkot, Pakistan, inspected on October 29-30, 1996. During the inspection our investigator determined that your firm manufactures surgical instruments. Surgical instruments are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. 21 CFR 820.181(a)

Failure of the device master record to include device specifications including appropriate drawings, composition, formulation, and component specifications, as required by 21 CFR 820.181(a). For example, dimensions for the blade length, angle, diameter of a drilled hole, and rivet size for scissors have not been included on the engineering drawing in the device master record.

Your response is not adequate. Although your response claims to have added dimensions on the drawings included in the Device Master Record, copies of the drawings were not submitted to confirm correction.

2. 21 CFR 820.80(a)

Failure to have written procedures for acceptance of components and inspecting, sampling, and testing components for conformance to specifications, and failure to test for conformance, where deviations from component specifications could result in the device being unfit for its intended use, as required by 21 CFR 820.80(a). For example, there was no mill analysis or check analysis of the stainless steel wire used for rivets in the manufacture of surgical instruments.

Your response is not adequate. Your letter states that your firm will request a Mill Analysis Certificate from the supplier of the stainless steel wire whenever they are purchased; however, no certificate was submitted. Additionally, although the letter claims to have added a boil test of the wire in the Device Master Record, the procedure was not submitted with the response.

3. 21 CFR 820.61(a)

Failure to establish adequate calibration procedures and to maintain records of calibration, as required by 21 CFR 820.61(a). For example, there are no calibration procedures for specific pieces of equipment, and no records have been kept, although the general calibration SOP requires records to be maintained.

Your response is not adequate. Although your letter claims to have amended SOP #24, Calibration, to include calibration procedures for each tool or equipment and maintaining calibration records, the procedures were not submitted.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, no pending applications for premarket approval (PMAs) or export approval requests will be approved and no premarket notifications [section 510(k)s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

Given the serious nature of the problems noted above, all surgical instruments manufactured by G.T. Surgical (PVT) Ltd. may be detained upon entry into the United States. In order to prevent the instruments from being subject to detention, you should provide the above referenced documentation supporting the GMP compliance status of your facility to this office. After your response is received for the three GMP deficiencies listed above and reviewed by this office, you will be notified of its adequacy.

The following FDA 483 observations, although not GMP violations, have been addressed by your quality assurance programs.

1. No procedure in place for conducting outside audits of raw material suppliers or testing labs.

2. Outside audits not conducted.

3. No maintenance standard operating procedures (SOPs) for equipment.

We understand that, in response to the investigator's observations listed above, your firm has written a new SOP for external audits of suppliers and laboratories, performed an audit of your stainless steel sheets and wires on November 4, 1996, and performed an audit of your testing laboratory on November 6, 1996. Furthermore, you have developed three more SOPs for the maintenance of equipment identified by the investigator.

If you have further questions on these requirements, please contact Ms. Cory Tylka at the General Surgery Devices Branch at phone: (301) 594-4595, or FAX: (301) 594-4636.

Sincerely yours,

for/ Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cancel. OPIP 2/20/97